§ 874.3495 Total ossicular replacement prosthesis.

(a) *Identification*. A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrance to the inner ear. The device is made of materials such as polytetrafluoroethylene, polytetrafluoroethylene with vitreous carbon fibers composite, porous polyethylene, or from a combination of these materials.

(b) *Classification*. Class II.

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.

(a) *Identification*. A prosthesis modification instrument for ossicular replacement surgery is a device intended for use by a surgeon to construct ossicular replacements. This generic type of device includes the ear, nose, and throat cutting block; wire crimper, wire bending die; wire closure forceps; piston cutting jib; gelfoam™ punch; wire cutting scissors; and ossicular finger vise.

(b) *Classification*. Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987]

§ 874.3620 Ear, nose, and throat synthetic polymer material.

(a) *Identification*. Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the suregon to conform to the patient's needs. This generic type of device is made of material such as polyamide mesh or foil and porous polyethylene.

(b) *Classification*. Class II.

§ 874.3695 Mandibular implant facial prosthesis.

(a) *Identification*. A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.

(b) *Classification*. Class II.

§ 874.3730 Laryngeal prosthesis (Taub design).

(a) *Identification*. A laryngeal prosthesis (Taub design) is a device intended to direct pulmonary air flow to the pharynx in the absence of the larynx, thereby permitting esophageal speech. The device is interposed between openings in the trachea and the esophagus and may be removed and replaced each day by the patient. During phonation, air from the lungs is directed to flow through the device and over the esophageal mucosa to provide a sound source that is articulated as speech.

(b) *Classification*. Class II.

§ 874.3760 Sacculotomy tack (Cody tack)

(a) *Identification*. A sacculotomy tack (Cody tack) is a device that consists of a pointed stainless steel tack intended to be implanted to relieve the symptoms of vertigo. The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure.

(b) *Classification*. Class II.

§ 874.3820 Endolymphatic shunt.

(a) *Identification*. An endolymphatic shunt is a device that consists of a tube or sheet intended to be implanted to relieve the symptons of vertigo. The device permits the unrestricted flow of excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption